

portions and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel; and

b) an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the length of the vascular access port and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein.

25. (Amended) An apparatus for facilitating vascular access comprising:

- a) a vascular access port defining an elongated tubular body of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having opposed proximal and distal end portions, the distal end portion adapted and configured for introduction into a blood vessel;
- b) an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port, the plug body having a length that is substantially equal to the length of the vascular access port so as to prevent blood flow into the lumen of the access port when the plug is engaged therein; and
- c) a locking mechanism associated with the proximal end of the elongated cylindrical plug body for releasably coupling the plug body to the vascular access port.

### **REMARKS**

Reconsideration of the above identified application in view of the preceding amendments and following remarks is respectfully requested.

By this amendment, Applicants have amended the specification and Claims 1 and 25 so as to more particularly point out and distinctly define the subject matter which Applicants regard as the invention. It is respectfully submitted that no new matter has been added to the subject application by these amendments nor have any new issues been raised. Support for these amendments is found throughout the specification and drawings.

In the Office Action, the Examiner objected to the drawings as failing to comply with 37 C.F.R. 1.83(a) and directed that the central core must be shown in the drawings or the feature cancelled from the claims. The central core is identified in Figs. 4, 6 and 8, by reference numerals 116, 216 and 316, respectively. However, reference numerals 116, 216 and 316 are not referred to in the specification. Therefore, Applicants have amended the specification to disclose the central core 116/216/316. Applicants respectfully submit that the objection to the drawings has been obviated and withdrawal thereof is requested.

The Examiner objected to the specification as failing to provide antecedent basis for the claimed subject matter. More specifically, the Examiner stated that nowhere in the disclosure is there mention of a central core. The central core is mentioned in the summary of the invention section of the specification on page 4, line 14. Additionally, as discussed above, Applicants have amended the specification to further disclose the central core. Therefore, Applicants respectfully submit that the objection to the specification has been obviated and withdrawal thereof is respectfully requested.

In the Office Action, the Examiner rejected Claims 1-12, 16 and 25-33 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,162,234 to Freedland et al. Freedland et al. disclose an adjustable button cinch anchor orthopedic fastener (1). Primarily, the fastener (1) includes an anchor (11), a collet (12), a hoop (14) and an adjustable collar

(112). As shown in Fig. 12, the collet (12) and the collar (112) surround the threaded shaft (111) of the anchor (11) and fasten to bone (3). Collet (12) includes internal threads (121) which engage with external threads (1111) formed on anchor (11). Collet (12) is a tubular which has a discontinuous outer wall formed by three angularly spaced-apart pawls (122). The pawls (122) are pressed radially inward when hoop (14) is advanced up the collet (12).

Applicants have amended Claim 1 to recite an apparatus for facilitating vascular access that includes, *inter alia*, an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel wherein the plug body has a length that is substantially equal to the length of the vascular access port and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein. This feature of the claimed invention is clearly illustrated in Figs. 3 and 4. Freedland et al. does not teach, disclose or suggest such a structural configuration. More specifically, the anchor of Freedland et al. do not have an outer diameter that is substantially equal to the inner diameter of the collet so as to prevent blood flow therebetween. Instead, there is a space between the two structures that will allow blood to flow therebetween. An advantage of the present invention is that blood is not allowed to stagnate within the lumen of the vascular access port.

Accordingly, Claim 1 and each of the claims depending therefrom, namely Claims 2-12 and 16, distinguish the subject invention from Fowler. Withdrawal of the rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

Applicants have amended Claim 25 to recite an apparatus for facilitating vascular access that includes, *inter alia*, a vascular access port that defines an elongated tubular body of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall. This feature of the claimed invention is clearly illustrated in Figs. 3 and 4. Freedland et al. do not teach, disclose or suggest such a structural configuration. The collet of Freedland et al. has a discontinuous outer wall and therefore, the collet is not capable of acting as a vascular access port which directs the flow of blood between its distal and proximal ends. Accordingly, Claim 25 and each of the claims depending therefrom, namely Claims 26-33, distinguish the subject invention from Freedland et al. Withdrawal of the rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

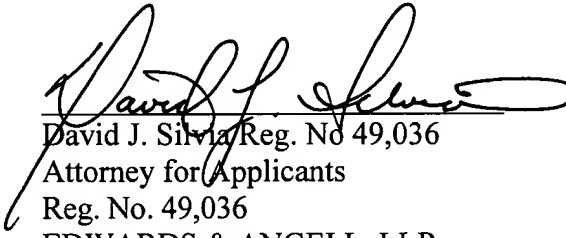
It is respectfully submitted that all of the claims pending in this application, namely Claims 1-12, 16 and 25-33 are directed to patentable subject matter, and allowance thereof is earnestly solicited.

Applicants' representative has reviewed the references cited by the Examiner but not relied upon in the rejection of specific claims. It is respectfully submitted that these references do not disclose or suggest, either alone or in combination, in whole or in part, the claimed invention.

If after reviewing this amendment, the Examiner believes that a telephone or personal interview would facilitate the resolution of any remaining matters the undersigned attorney may be contacted at the number set forth hereinbelow.

Respectfully submitted,

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**VERSION WITH MAKINGS TO SHOW CHANGES MADE****IN THE SPECIFICATION:**

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Please replace the paragraph beginning on page 1, line 9 with the following amended paragraph:

(Amended) The elongated cylindrical plug body 110 has an outer diameter  $D_2$  that is substantially equal to an inside diameter  $D_1$  of the lumen 128 of the vascular access port 120. Therefore, when the plug body 110 is inserted into the lumen 128 of the access port 120, during periods in which the dialysis process is suspended, the flow of blood 132 into the access port 120 is prevented. Additionally, since the length  $L_2$  of the plug body 110 is substantially equal to the length  $L_1$  of the access port 120, stagnant blood 143 will not remain in the lumen 128 nor will residual debris accumulate therein. Plug body 110 also includes a hollow central core 116 which serves to increase the flexibility of the plug body 110.

Please replace the paragraph beginning on page 11, line 6 with the following amended paragraph:

(Amended) Referring now to Figs. 5 and 6, there is illustrated an apparatus for facilitating vascular access constructed in accordance with another embodiment of the subject invention and designated generally by reference numeral 200. Apparatus 200 includes a vascular access port 220 and an elongated cylindrical plug body 210 and is substantially similar in structure and function to apparatus 100 shown in Figs. 3 and 4. It differs however, in that the locking mechanism 214 includes helical external threads 244 associated with the outer diameter  $D_2$  of the plug body 210. Additionally, in this

embodiment, internal threads 222 are associated with the lumen 228 of the access port 220 and are adapted and configured for receiving external threads 244 of plug body 210. Like apparatus 100, the locking mechanism is engaged by grasping handle portion 212 and rotating the plug body 210 clockwise, as shown by directional arrow Z in Fig. 6. Plug body 210 also includes a hollow central core 216 which serves to increase the flexibility of the plug body 210.

Please replace the paragraph beginning on page 11, line 17 with the following amended paragraph:

(Amended) Referring now to Figs. 7 and 8, there is illustrated an apparatus for facilitating vascular access constructed in accordance with still another embodiment of the subject invention and designated generally by reference numeral 300. Apparatus 300 includes a vascular access port 320 and an elongated cylindrical plug body 310 and is substantially similar in structure and function to the apparatus shown in Figs. 3 and 4. This apparatus differs however, in that locking mechanism 314 includes at least one protuberance 344 disposed on the proximal end 342 of the plug body 310 and adapted and configured for insertion into a corresponding recess 322 disposed at the proximal end 338 of the vascular access port 320. The locking mechanism is engaged by grasping handle portion 112 and linearly inserting plug body 310 into vascular access port 320, as shown by directional arrow y, until protuberance 344 is positioned within corresponding recess 322. Plug body 310 also includes a hollow central core 316 which serves to increase the flexibility of the plug body 310.

**IN THE CLAIMS:**

Please replace Claims 1 and 25 with the following amended claims:

1. (Twice Amended) An apparatus for facilitating vascular access comprising:
  - a) a vascular access port defining an elongated tubular body of predetermined length with a central lumen having opposed proximal and distal end portions and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel; and
  - b) an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the length of the vascular access port and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein.



25. (Amended) An apparatus for facilitating vascular access comprising:

a) a vascular access port defining an elongated tubular body of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having opposed proximal and distal end portions, the distal end portion adapted and configured for introduction into a blood vessel;

b) an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port, the plug body having a length that is substantially equal to the length of the vascular access port so as to prevent blood flow into the lumen of the access port when the plug is engaged therein; and

c) a locking mechanism associated with the proximal end of the elongated cylindrical plug body for releasably coupling the plug body to the vascular access port.